

REMARKS

Introductory Comments

Reconsideration of the above-identified application in view of the above amendments and arguments set forth is respectfully requested.

Claims 17-27 are pending and under consideration. Claims 17-27 have been amended as explained below. No new matter has been added as a result of these amendments.

Objection to the Specification

The specification is objected to for improperly incorporating by reference the cited patents. Specifically, the Examiner states that Applicants cannot use the omnibus language in the incorporation by reference language on pages 9 and 37 since they fail to teach with detailed particularity just what information Applicants seek to incorporate and where in the reference this information is located. Applicants respectfully traverse the objection.

As noted on page 9, all of the cited patents listed on page 9 are discussed in the instant specification. For example, U.S. Patent No. 5,795,784, which is listed on page 9, is discussed on page 10 with particularity. On lines 1-4, the specification states that this patent discloses a process path similar to the process path as disclosed in the instant specification. Similarly, all of the cited references are discussed in the instant specification as to their significance. Therefore, despite the omnibus language, detailed references have been made to each of these references. Applicants respectfully submit that one of ordinary skill in the art would be able to locate exactly where the significant information is in the cited references (e.g., U.S. Patent No. 5,795,784 is cited on page 9 with reference to the process path and one of ordinary skill in the art would be able to read the patent and know where this process path is discussed).

Applicants further submit that the cited patents disclose analyzers, assays or methods for using such which are relevant to the analyzers, assays or

methods of using as disclosed in the instant specification and which are claimed herein. The relevant information for such analyzers, assays or methods for using such are disclosed throughout the cited patents. Providing a large list of exactly where each information is listed on which line of these patents would be inefficient and impractical as practically the whole disclosures are relevant. Likewise, the incorporation by reference on page 37 of the instant application is proper.

Applicants respectfully submit that method of incorporation by reference used by Applicants is now common practice. Additionally, Applicants respectfully note that the quotation from *Advanced Display Systems Inc. V. Kent State University*, 54 U.S.P.Q.2d at 1679 (Fed. Cir. 2000) relates not to the adequacy of the disclosure in a pending patent application, but rather relates to the adequacy of the disclosure in a prior art reference being cited against a patent application. This is clear from the text introducing the portion quoted by the Office Action:

Section 102(b) provides that "a person shall be entitled to a patent unless the invention was patented or described in a printed publication . . . more than one year prior to the date of the application." 35 U.S.C. § 102(b) (1994). Accordingly, invalidity by anticipation requires that the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation.

Incorporation by reference in the context of a pending application is a completely different matter, as its treatment in the M.P.E.P. clearly demonstrates:

Instead of repeating some information contained in another document, an application may attempt to incorporate the content of another document or part thereof by reference to the document in the text of the specification. The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed.

M.P.E.P. §2163.07(b). In fact such incorporation, where possible, is encouraged, with Patent and Trademark Office practices being such as to allow the applicant to use such references while being able to amend the specification to add

incorporated disclosure should it ultimately be deemed necessary (depending on the type of publication being incorporated and a determination as to whether or not the incorporated material is deemed “essential” to the invention recited in the allowed claims). M.P.E.P. §608.01(p). As the C.C.P.A. said long ago when indicating the need to expressly state that another document is “incorporated by reference”:

As the expression itself implies, the purpose of “incorporation by reference” is to make one document become a part of another document by referring to the former in the latter in such a manner that it is apparent that *the cited document is part of the referencing document as if it were fully set out therein.*

(Emphasis added). *In re Lund*, 153 U.S.P.Q. 625, 631 (C.C.P.A. 1967), also quoted in *In re de Seversky*, 177 U.S.P.Q. 144, 147 (C.C.P.A. 1973) (cited in M.P.E.P. §608.01(p)).

If the disclosure incorporated by reference is deemed to be required text in this specification based on claims which are to issue, Applicants will amend the specification to set it forth pursuant to M.P.E.P. §608.01(p).

Accordingly, Applicants respectfully request withdrawal of the objection to the specification for these reasons.

Rejection of Claims 17-27 Under 35 U.S.C. § 112,

First Paragraph – Written Description

Claims 17-27 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. It is alleged that these claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one of skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, the Examiner asserts that the specification fails to describe an analyzer for amplifying biological products. Applicants respectfully traverse this rejection.

Applicants have described the general structures or features of analyzers as described through the incorporation by reference starting on page 7 and via the number of cited references noted by the Examiner on page 9. Thus, the term "analyzer" has been claimed and described in a broad sense in the specification. The specifics for the amplification of biological products and the assays of biological products are known in the art. The uniqueness of Applicants' analyzer is from the biological sample in connection to the conductors, circuit and voltage that are claimed. Applicants submit that it is inefficient to describe every detail that is remotely germane to the invention.

Notwithstanding the above, in an effort to expedite prosecution of the instant application, Applicants have amended the claims by using the well-accepted Jepson format. Therefore, it is now clear that the claims are directed to an improved analyzer wherein the improvement comprises the limitations set forth in the claims. Therefore, Applicants respectfully submit that based on the amendment, the rejection of the claims based on failing to comply with the written description requirement is now moot.

For these reasons, Applicants respectfully request withdrawal of the rejection of claims 17-27 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Rejection of Claims 17-27 Under 35 U.S.C. § 112,
First Paragraph - Enablement

Claims 17-27 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. It is alleged that these claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one of skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, the Examiner asserts that based on the broad claim language, the claims are interpreted to encompass amplification methods such as hybridization that are known to be problematic. The Examiner contends that

the specification does not comply with the enablement requirement since the specification fails to disclose the particulars of such methods.

As noted above, Applicants have amended the claims by using the Jepson format, wherein the claimed limitations are focused. Therefore, Applicants respectfully submit that the amendment has overcome the enablement rejection. For these reasons, Applicants respectfully request withdrawal of the rejection of claims 17-27 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

Rejection of Claims 17-27 Under 35 U.S.C. § 112, Second Paragraph

Claims 17-27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner states that it is unclear what about the DNA or RNA is to be determined. Also, the Examiner points out that in claim 17, the recitation “the also” is indefinite, in claim 19, the “sample” is claimed but claim 17 from which claim 19 depends does not positively claim the “sample”, and claims 17-27 omit essential structural cooperative relationship between the elements.

Applicants have amended the claims by using the Jepson format as pointed out above. Applicants have also amended the claims to remedy the indefiniteness listed above by deleting the recitation of “the also” for claim 17, to not positively claim the “sample”, and to provide essential cooperative relationships between the elements.

As stated above, claims 17-27 are amended to merely place claim 17 in a Jepson format, to positively claim the structural features of the analyzer by replacing the functional language, to provide essential structural cooperative relationship between the elements and/or to cure the indefiniteness pointed out by the Examiner. Although all of the amendments which provide the essential structural cooperative relationship between the elements are evident based on the definitions of the elements, clear support from the specification for these amendments are as follows: Claim 21: page 12, lines 1-10; claim 22: page 15,

lines 3-19; claim 23: page 54, line 29 to page 56, line 8; claim 24: page 56, line 3 to page 57, line 10; and claim 25: page 54, line 18 to page 55, line 22.

Applicants would like to point out to the Examiner that claim 17 has been amended to positively recite that the first conductor and the second conductor are electrically connected to the container of the improved nucleic acid analyzer.

Applicants respectfully submit that the amendment has overcome the rejection of the claims for indefiniteness. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 17-27 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regard as the invention.

Rejection of Claims 17-27 Under 35 U.S.C. § 102(b)

Claims 17-27 are rejected under 35 U.S.C. § 102(b), as being anticipated by a laboratory comprising a microfuge, eppendorf tubes, a HVAC system, a pippettor and an electrician.

Specifically, the Examiner asserts that based on the problems of the claim language, the claims are interpreted as reading on a laboratory comprising a microfuge, eppendorf tubes, a HVAC system, a pippettor and an electrician.

Applicants respectfully traverse this rejection. Applicants respectfully submit that the courts have determined that the claims should be read in light of the specification and that it is evident from the specification that the claims are not meant to read broadly on the combination of elements as the Examiner applied.

Moreover, Applicants submit that even if any claims had been allowed to be interpreted in a manner as that above, claims 17-27 have now been amended to overcome such an interpretation.

First, as noted above, the claims now are in a Jepson format such that the claims are specifically directed to an improved nucleic acid analyzer for amplifying and determining a DNA or RNA, with the listed improvements. The claims no longer can be construed as reading on something other than a nucleic acid analyzer for amplifying and determining a DNA or RNA.

Second, as noted above, the claims have been amended to require that the first conductor and the second conductor are electrically connected to the container which holds the sample comprising nucleic acid for identification and analysis.

For these reasons, Applicants respectfully request withdrawal of the rejection of claims 17-27 under 35 U.S.C. § 102(b), as being anticipated by a laboratory comprising a microfuge, eppendorf tubes, a HVAC system, a pipettor and an electrician.

CONCLUSION

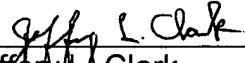
Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. Sections 112 and 102. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Should the Examiner have any questions concerning the above, he is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

If any additional fees are incurred as a result of the filing of this paper or the related RCE, authorization is given to charge deposit account no. 23-0785.

Respectfully submitted,
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